

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

Recall of oneHbA1c FS lot 23640

Defective reagent 2 in oneHbA1c FS reagent lot 23640

Date:	December 4, 2017
Product and Lot:	oneHbA1c FS, Cat. No. 1 3329..., lot 23640
Kit lots:	60115759, 60115799, 60115924, 60115975, 60115976, 60116203, 60116247, 60116473, 60116852, 60116983, 60117119, 60118685, 60118914, 60119049, 60119211, 60120620
Explanation:	This is a safety precaution. Using oneHbA1c FS Lot 23640, more specifically the above mentioned kit lots, might lead to difficulties with calibration because of defective reagent 2. Measurement of patient samples might – in highly pathological HbA1c range (11.0-16.0 % or 100-150 mmol/mol) – deliver falsely decreased results.
Impact on patient results:	Falsely low results for patient samples are possible, whereas recovery of dedicated controls is found within acceptance range.
Measures:	<ul style="list-style-type: none">• Please inform all users about the recall of oneHbA1c FS lot 23640 immediately• Exchange and immediate stop further measurements with oneHbA1c FS lot 23640. Existing stock must be discarded. DiaSys offers replacement for the affected number of kits.• Please discuss with the head of laboratory if patient values determined with oneHbA1c FS lot 23640 should be repeated.

DiaSys has announced this field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

Under current regulations we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all concerned customers. Please send it back by fax or as scan until **15.12.2017**.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Kind regards

Sabine Befard
Product Management Reagents